



Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Submission to OMB for Review and Approval;
Public Comment Request**

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Stem Cell Therapeutic Outcomes Database

OMB #0915-0310 -- Revision

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111–264 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA’s Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. HRSA uses the information in order to carry out its statutory

responsibilities. Information is needed to monitor the clinical status of transplantation and to provide the Secretary of HHS with an annual report of transplant center-specific survival data. The increase in burden, as reflected in this revised submission request, is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Estimates of Average Annualized Hour Burden:

Form Name	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Baseline Pre-Transplant Essential Data (TED)	200	38	7,600	1	7,600
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	29	5,800	1	5,800
100-Day Post-TED	200	38	7,600	0.85	6,460
6-Month Post-TED	200	31	6,200	1	6,200

12-Month Post-TED	200	27	5,400	1	5,400
Annual Post-TED	200	104	20,800	1	20,800
Total	200		53,400		52,260

Dated: December 5, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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